Background

The National Surgical Adjuvant Study of Breast Cancer 07 (N-SAS BC 07) is a randomized clinical trial (RCT) in women over 70 years with HER2-positive primary breast cancer (Sawaki M, et al. Jpn J Clin Oncol 2011;41:791-8).

There are few RCTs examining adjuvant treatment in elderly breast cancer patients.

While obtaining informed consent is essential for participation in clinical studies, there is little information on the frequency of agreement to participate among elderly patients.

Furthermore, elderly patients might have specific reasons to decline participation.

There have been no previous RCTs in elderly breast cancer patients, and it was not possible to predict the number of patients who would not assign informed consent. The patients were also registered in a cohort study to prospectively evaluate the subsequent treatment options and prognosis (07-Cohort) (Fig. 1).

In 07-Cohort study, patients were treated with Investigator’s choice.

This study examined the obtained of informed consent for N-SAS BC 07 RCT and the reasons for declining participation in the RCT at registration, and compared the clinicopathological backgrounds between 07-RCT group and 07-Cohort groups.

Materials & Methods

The primary aim of the N-SAS BC 07 was to investigate the benefit of trastuzumab monotherapy compared with the combination of trastuzumab and chemotherapy.

Key inclusion criteria were as follows:

- women between 70 and 80 years old with HER2-positive breast cancer
- women who received curative operation
- stage I to IIIA with sufficient organ function

Furthermore, elderly patients might have specific reasons to decline participation.

The estrogen receptor (ER) positive rate in 07-Cohort group was 37.0% and 52.5%, respectively, which indicated that the ER positive rate was higher in 07-Cohort group (p=0.01, z² test).

Results

398 eligible patients have been recruited. We show the patient characteristics (Table 1).

Informed consent to participate in N-SAS BC 07 has been obtained from 275 patients (69%) and 123 patients (31%) who declined to participate. In 07-Cohort, patients were randomized to receive either trastuzumab plus chemotherapy or trastuzuamab monotherapy (07-RCT group).

A cohort study (07-Cohort group) was planned for patients who did not assign informed consent. The patients were also registered in a cohort study to prospectively evaluate the subsequent treatment options and prognosis (07-Cohort) (Fig. 1).

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This study examined the obtained of informed consent for N-SAS BC 07 RCT and the reasons for declining participation in the RCT at registration, and compared the clinicopathological backgrounds between 07-RCT group and 07-Cohort groups.

Objective

1. To examine the obtained of informed consent for N-SAS BC 07-RCT and the reasons for declining participation.

2. To investigate what clinicopathological backgrounds influenced elderly patients to participate this RCT

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Table 1. Patient’s Characteristics

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</table>

Summary

Since N-SAS BC 07 investigated whether elderly patients with HER2-positive breast cancer should undergo chemotherapy, we expected the rate of consent for registration to be small. However, almost 70% of the patients accepted informed consent.

The most common reason to decline participation in N-SAS BC 07-RCT was “cannot choose the treatment option” and the majority refused chemotherapy.

ER positivity was higher in the 07-Cohort group, which suggested that ER expression in the patients with HER2-positive breast cancer might influence their decision to undergo chemotherapy.